

WHAT IS CLAIMED IS:

1. A delivery system for delivering a therapeutically effective amount of a predetermined genetic material to myocardial cells of a chosen location of a patient's heart, said genetic material being selected for the function of increasing the amplitude of the patient's cardiac signal so that it can be better sensed by an electrode, comprising:
  - 5 a supply of said genetic material;
  - reservoir means for containing said genetic material; and
  - 10 delivery means for delivering said genetic material from said reservoir to said myocardial cells,
  - 15 thereby increasing the amplitude of the cardiac signal and improving the signal to noise ratio that can be sensed by a pacemaker.
2. The delivery system of claim 1, wherein said supply of genetic material comprises a bolus of ion channel protein genetic material selected for the function of increasing the amplitude of the cardiac signal.
- 20 3. The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal end portion, and said reservoir means is located in said distal end portion.
- 25 4. The delivery system of claim 3, wherein said distal end portion comprises a hollow helical element forming an interior, and said reservoir means comprises said interior with said supply therein.
- 30 5. The delivery system of claim 1, wherein said delivery means comprises a catheter with a lumen for delivering said genetic material therethrough, said catheter having a distal tip communicating with said lumen for

contacting said plurality of cells in the proximity of said electrode with said genetic material.

6. The delivery system of claim 5, wherein said distal tip is a hollow helical needle tip.

5 7. The delivery system of claim 5, wherein said catheter is a transvenous endocardial catheter.

8. The delivery system of claim 1, wherein said reservoir contains a supply of 0.1-10 ml of said genetic material.

10 9. The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal portion and an end tip, and wherein said reservoir means is contained in said distal portion, and further comprising force means for forcing said genetic material from said  
15 reservoir means and out of said end tip.

10. The delivery system of claim 9, wherein said force means comprises a stylet.

11. The delivery system of claim 1, wherein said delivery system comprises a hollow helical screw-in element  
20 loaded with a bolus of said genetic material.

12. The delivery system of claim 11, wherein said element comprises ports for egress of said genetic material into said identified cardiac location when said element is screwed into said location, and further comprising soluble  
25 plugs in said ports to maintain them normally closed but which dissolve when said element is positioned within said patient's heart.

13. The delivery system of claim 1, wherein said predetermined genetic material is DNA or RNA, and imparts

chronic change in ion channel expression in said cardiac cells.

14. The delivery system of claim 1, wherein said delivery means comprises a catheter with a distal end  
5 portion, and said reservoir means is located in said distal end portion.

15. The delivery system of claim 13, wherein said DNA or RNA encodes an ion channel protein.

16. The delivery system of claim 15, wherein said  
10 ion channel protein is a sodium channel protein.

17. The delivery system of claim 16, wherein said sodium channel protein is hH1.

18. The delivery system of claim 1, wherein said predetermined genetic material is protein, and imparts acute  
15 change in sodium channel expression in said cardiac cells.

19. The delivery system of claim 18, wherein said protein is an ion channel protein.

20. The delivery system of claim 19, wherein said ion channel protein is a sodium channel protein.

21. The delivery system of claim 20, wherein said  
20 sodium channel protein is hH1.

22. An implantable delivery system for delivering doses of a therapeutically effective amount of a predetermined genetic material to myocardial cells in a  
25 chosen location of a patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in the myocardial cells to which it is delivered;

a catheter, said catheter having a distal tip portion for engaging the cells of said chosen location and delivering thereto said genetic material;

reservoir means for holding said supply of genetic material and providing it to said distal tip portion of said catheter; and

delivery means for delivering a therapeutically effective amount of said genetic material from said reservoir means through said distal tip portion to said chosen location.

23. The system as described in claim 20, further comprising:

control means for controlling operation of said delivery means to deliver respective said doses.

24. The implantable delivery system of claim 23, wherein said control means comprises initiating means for initiating delivery of said genetic material, said initiating means comprising an external programmer.

25. The implantable delivery system of claim 23, wherein said control means comprises automatic means for automatically initiating delivery of said genetic material.

26. An implantable delivery system for delivering predetermined genetic material to cardiac cells adjacent to a pacing electrode positioned against the inner wall of a patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in cardiac cells to which it is delivered;

a catheter, said catheter having a distal tip portion for engaging said cardiac cells and delivering thereto said genetic material;

reservoir means for holding said supply of genetic material and providing it to said distal tip portion of said catheter; and

delivery means for delivering a therapeutically effective amount of said genetic material from said reservoir means through said distal tip portion to said cardiac cells.

27. The implantable delivery system of claim 26, wherein the distal end of said distal tip portion further comprises a pacing electrode.

28. The system as described in claim 26, further comprising:

control means for controlling operation of said delivery means to deliver respective said doses.

29. The implantable delivery system of claim 26, wherein said control means comprises initiating means for initiating delivery of said genetic material, said initiating means comprising an external programmer.

30. The implantable delivery system of claim 26, wherein said control means comprises automatic means for automatically initiating delivery of said genetic material.

31. An implantable system for pacing a patient's heart and for delivering a predetermined genetic material to cardiac cells adjacent to a pacing electrode positioned in said patient's heart, comprising:

a supply of genetic material of the class having the property of increasing the expression of ion channels in cardiac cells to which it is delivered;

a catheter, said catheter having proximal and distal ends, a lumen through at least a part thereof and connecting to said distal end, a pacing electrode positioned at said distal end for engaging said patient's heart wall,

said electrode having a channel therethrough in communication with said lumen, and a conductor connecting said proximal end to said electrode,

5 a pulse generator connected electrically to said conductor at said catheter proximal end for delivering pace pulses to said electrode,

reservoir means for holding said supply of genetic material, and

10 delivery means for delivering said genetic material from said reservoir to said lumen, whereby said material passes through said lumen and said channel to said heart wall.

32. The implantable system of claim 31, wherein said reservoir is mounted in said pulse generator.

15 33. The implantable system of claim 31, wherein said delivery means is passive.

34. The implantable system of claim 31, wherein said delivery means comprises a pump.

20 35. The implantable system of claim 31, wherein said electrode is substantially concentric with respect to the catheter axis, and the channel passes through the center of said electrode.